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EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,601

Applicant(s)

BUCAY-COUTO ET AL.

Examiner

Timothy E. Betton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4 sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-21 and 33-36 are currently pending and are the subject of this Office Action. Applicants' have withdrawn claims 22-32 in the Remarks filed 21 September 2006.

Election/ Restrictions

Applicant's election of Group I, claims 1-21 and 33-36 in the reply filed on 21 September 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The election is drawn to a dosage form and method of forming said dosage form, classified, for example when the dosage form is an insertable or injectable chemical ablation agent with a biodegradable binder.

Claim Rejections – 35 USC § 112- 1ST Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue.

In re Wands, set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC§ 112, 1st

Paragraph:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present
5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed
8. The level of skill in the art

The nature of the invention

The nature of the invention is complex. The invention involves the administration of chemical agents on tissue component/cell tissue. Tissue presents with a multiplicity of physiological factors that may manifest variant results when a system of chemical

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agents are administered thereto. Compromised conditions of tissue, i.e., cell proliferation, cancerous cells, hypertrophy, etc. may present additional factors, which require specific modifications to chemical agents administered, thereby presenting complexities in the dynamics of administration

The state of the prior art

Some chemoablation models, techniques and agents are known in the art.

The predictability or lack thereof in the art

The unpredictability in the art is significant because of dosage administration issues that persist in the art. In the instant specification (paragraph [0020], page 4), Applicants' disclose that, "[A] wide range of biodisintegrable binder concentrations are utilized in the formulations of the present invention, with amounts varying based on the characteristics of both the ablation agent and the biodisintegrable binder, among other considerations."

In Rehman et al., in a particular embodiment involving ethanol as an ablative, it states, "to date, [...]. In urology, chemoablation is still very much in the investigational stage for both the prostate and the kidney. A significant drawback is that even in the gel form, the spread of the chemoablative substance through the tissue is irregular and unpredictable. In the future, chemoablation may become a more effective modality by combining it with radiofrequency or other energy sources.

The amount of direction or guidance present

The amount of direction or guidance present is deficient within the instant claims. The instant specification, extrapolates on certain embodiments of adaptation (claim 8) of

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the dosage form for injection or insertion, the amount lacks the appropriate detail necessary. Proper determination is uncertain because of critical methods, processes, or steps that are not so apparent, therefore making proper direction and guidance uncertain.

Due to the nature of the invention, skilled direction and guidance should be evident and of such sufficient comprehensibility that one of said skill could at once interpret the embodiments facilitated by such direction and guidance. In instant invention, the amount of sufficient direction and guidance is lacking. There is no generalized scheme by which to perform that, which is disclosed in subject claim 1, i.e., ablation and necrosis of said tissue.

The presence or absence of working examples

There is the presence of working examples insofar as compounding examples, disclosing specific dosage strengths, quantities, and all other related measurements in association with pharmaceutical formulations. The working examples of subject application are drawn specifically to pharmacy technology/ the preparation of therapy drug delivery system. The embodiment discloses the processes by which various dosage forms are compounded and manufactured. However, there is absence as to how these formulations ablate and/or necrotize tissue.

The breadth of the claims

The breadth of the claims encompasses a broad embodiment of said subject matter.

The quantity of experimentation needed

The quantity of experimentation needed is substantial. As disclosed within the instant specification (paragraph [0020], pg 4), there presents a multiplicity of factors in regard to disclosed agents used in said formulation. Among other considerations, bioavailability is a central factor that varies from individual to individual manifesting with such conditions in need of said treatment. However, disclosures in the specification and claim set are inconclusive, therefore more experimentation is required.

The level of skill in the art

The level of skill in the art is reasonably substantial with necessary on going research required.

Again, as stated above in MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. As a result of the explanation disclosed above, the enablement requirement is not adequately satisfied in reference to the scope of the alleged invention. Consequently, the experimentation required is extensive due to the complex nature of the subject matter.

Claim Rejections –35 USC§ 112, 2ND Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-21 and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 discloses a chemical **ablation** agent in a concentration effective to cause **necrosis** of said tissue.

For exemplary purposes only, **ablation** is defined as a **removal or excision**. Ablation is usually carried out surgically. The word ablation comes from the Latin *ablatum* meaning to carry away. However, the term **necrosis**, in contrast, is defined simply as **the death of living cells or tissue**. Necrosis can occur due to ischemia (lack of blood flow). Therefore, in subject claim 1 there is a direct conflict in scope of alleged invention. Ablative tissue may present necrosis, however necrosis does not necessarily equivocate to an ablative condition. Ablation conventionally suggests removal or excision via surgical instrument used for excising. Ablation does not conventionally suggest removal or excision by direct administration of a chemical agent formulation to compromised tissue. Necrosis, on the other hand, may present with portions of necrotized tissue breaking free from compromised region, cycling through the circulatory system. However, this is not ablation in the conventional sense.

The specification does not conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as the alleged invention according to instant claim 1. It is indeterminate and unclear to the Examiner as to which component of subject claim 1, the preamble or the body, that the Applicants' intend to have encompass the metes and bounds of the invention.

Claim Rejections – 35 USC § 103(a) Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-21 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al., (USPN 6905475) and Escandon et al., (USPN 7015253) in view of Unger et al. (USPN 5469854 and USPN 5733572).

Hauschild et al. teach a " Method and surgical instrument for treating prostate tissue including a surgical instrument having a main body, a needle deployment port, a needle, first and second handles and a lockout release mechanism to limit needle extension. Additionally, a kit includes the surgical instrument, together with a

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cystoscope, and optionally a syringe and reservoir of ethanol. The method includes needle-less injection and visualizing the ethanol injection by delivering both an echogenic agent and ethanol either by needle or needle-less injection or by providing an ultrasonically visible marker near the tip of the ethanol delivery cannula. The method also includes extending the needle transversely of the instrument housing using a link assembly (Abstract)."

In patented claim 1, Hauschild et al., teach a method of injecting a drug into prostate tissue. Column 3, line 30 specifically teaches the use of a surgical instrument: the scope allows visual positioning of the needle port against the urethra adjacent to the lobe of the prostate to be treated. The needle is advanced one detent click at a time to place the needle tip in the adenoma. A small volume of an active ingredient such as anhydrous alcohol is slowly injected into the tissue. The urethral lumen may be continuously irrigated while the ethanol is being administered. The embodiment suggests a process similar to a manner of **necrotizing** compromised tissue. However, in other aspects of the invention in Figures 9 and 10, column 6, lines 35-40, there is a disclosure of **transurethral ablation**. Furthermore, in column 1, line 39-57, **ablation** is initially disclosed but in relation to laser treatments. Additionally, it is disclosed that **ablation** is associated with the process of **surgically damaging** prostate tissue. One of ordinary skill in the art would readily recognize that as a result of surgically damaging prostate tissue, there is certain to be necrotizing of said tissue. However, **removal or excision** of such compromised tissue is not as apparent. The dosage form of the active

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ingredient as disclosed in a specific embodiment is a **sterile semi-solid** in consistency, i.e., GELFOAM® Sterile Powder.

In column 10 of Hauschild et al., patented claim 1 is obvious over subject claim 8, which discloses an injection or insertion into the tissue via a jet injector. The referenced patent teaches a surgical instrument disclosed in column 5, lines 49 to 55 **similar to the jet injector** apparatus disclosed in instant claim 8. In addition, said instrument contains a disclosure as to make the needle more visible on ultrasound and ways to make the fluid delivered more visible which is similar to the disclosure of a **contrast agent** in instant claim 21.

Escanden et al. teach, "The present invention provides treatment regimens for treating diseased prostate tissue, including the steps of **chemically ablating prostate tissue and coadministering an antiandrogen**. In some embodiments, injection of ethanol, or an injectable gel comprising ethanol, into prostate tissue, chemically ablates prostate tissue. Steroidal and non-steroidal antiandrogens are suitable antiandrogens. One suitable non-steroidal antiandrogen is bicalutamide. The treatment regimen is suitable for treatment of prostate tissue diseases including benign prostatic hyperplasia and prostatic carcinoma. The invention further provides a treatment regimen for treating benign prostatic hyperplasia, including the steps of **damaging prostate tissue** and coadministering an antiandrogen. Also provided by the present invention is a kit for treating a human male, including a means for **necrosing prostate tissue**, an antiandrogen drug, and a means for administering the antiandrogen drug. A kit including a first surgical device for delivering a **chemoablation fluid to prostate tissue**

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transurethrally, an antiandrogen drug such as bicalutamide, and a second surgical device for administering the antiandrogen drug, is further provided (Abstract)."

Specifically, claims 1, 20, and 21 in instant application are obvious over Escanden *et al.* In column 5 and 6 of referenced patent, several embodiments of **chemoablation** are cited. In one embodiment, the present invention provides a treatment regimen for treating diseased prostate tissue. The treatment regimen includes the steps of **chemically ablating prostate tissue** sufficiently to elicit a **reparative process** in the absence of further treatment; and coadministering a therapeutically effective amount of an antiandrogen.

"As used throughout this specification, the terms **"ablate," "ablation" or "ablating" of tissue means causing a reduction in tissue mass. One suitable manner of ablating tissue is by causing a decrease in the number of tissue cells.** The phrase "chemical ablation" includes processes whereby tissue mass is reduced by action of a chemical or biological agent on the tissue. The size of the prostate is reduced relative to its size prior to treatment by the treatment regimen. The treatment regimen is suitable for treatment of prostate tissue diseases including BPH and prostatic carcinoma . One suitable procedure for chemically ablating prostate tissue in accordance with the treatment regimen is by injection of ethanol (absolute alcohol) into the prostate to be treated. Ethanol preferably is injected deeply into prostate tissue through a needle that is positioned transurethrally, such as in the procedure known as transurethral ethanol ablation of the prostate (TEAP). The ablating action of ethanol is

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due to several processes, including dehydration of cells, coagulation of proteins, and thrombosis of vessels that feed the tissue.”

Column 17, the surgical instrument called a PROSTAJECT is similar in scope to the **jet injector** as disclosed in instant claim 8. Further, on line 11 the means for **necrosing prostate tissue** is disclosed. In particular, the **ethanol** is intended to be used as **an ablating or necrosing agent**, and the antiandrogen is intended to be coadministered according to any of the treatment regimens described above. The antiandrogens described above are suitable for the combination medicament. Bicalutamide in particular is a suitable non-steroidal antiandrogen (column 18). In column 10, line 11 an additive for enhancing the **visibility of the chemoablation fluid** may be incorporated via specialized dyes. This similarity is found like-wise in instant claim 21, which discloses imaging via **contrast agents**.

Hauschild et al. do not directly teach specific claims in regard to necrotizing prostate tissue, however a combination of a contrast agent (i.e., visible marker) and an ultrasonic beacon are disclosed within patented claims in order to facilitate detecting and determining amount of agent to specific site of prostate tissue via surgical instrument. Further, referenced patent does not teach an identical model of a jet injector as disclosed in instant claim 8, however the apparatus used is significantly similar in design, operation, and effect. There is no specific mention of **dosage form shapes or biodisintegrable binders** as is disclosed in instant claims 1-6, 20-21, 33-36, and 7-19, respectively.

Escanden et al. does not teach the identical embodiment of contrasting agents as disclosed in instant application. Further Escanden et al does not teach treatment to other body regions except to prostate tissue. Additionally, there is no specific mention of **dosage form shapes or biodisintegrable binders** as is disclosed in instant claims 1-6, 20-21, 33-36, and 7-19, respectively.

However, The Examiner refers to Unger et al., which discloses, "Methods of and apparatus for preparing gas-filled liposomes are described. Gas-filled liposomes prepared by these methods are particularly useful, for example, in ultrasonic imaging applications and in therapeutic drug delivery systems." Where Hauschild et al and Escanden et al. are drawn to the actual use of a disclosed therapeutic delivery system, respectively, specifically for prostate tissue, Unger et al. encompasses all other embodiments disclosed within instant claims.

In column 4 under Brief Description of the Figures of referenced patent, **adaptation** of ablative formulation is adequately and comprehensively disclosed. As is lacking in subject claim 8 and the corresponding portion of the instant specification of the instant application, Unger et al. properly disclose what is obvious from Applicants' disclosure in claim 8. Additional **adaptation** disclosures are found in column 16, line 14-67, column 17, lines 1-18). Though Unger et al. patented invention is drawn to methods of and apparatus of preparing a formulation, the disclosure within column 4 teaches specific adaptation techniques in order to prepare an injectable or insertable dosage form for **chemoablation**. Unger et al. further teaches the functionality of the liposome dosage form with detailed explanations disclosed within column 11 to 15 of patented

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reference. It suggests the motivation to modify the matrical structure and pharmacodynamics (dosage form structure and shape and/or phase) of the liposome by making them single bilayer and/or multilamellar (column 11, line 52), viscosity modifiers (column 13, line 27), molecular weight polymers of 800 and 8000 (column 13, line 31,32) for increased stability of dosage form structure, etc. **Biodisintegrable** disclosures of liposomes in their various modifications are also disclosed (column 14-18). As the motivation was obvious to present various dosage form shapes and biodisintegrable binders in subject claims 1-6, 20-21, 33-36, and 7-19, respectively, so is the motivation obvious to combine the teachings of Hauschild and Escanden et al. with the specific dosage formulation disclosure of Unger et al. Furthermore, Unger et al. teach the expansive use of patented invention with a **multiplicity of classes** of drugs that can be formulated into said patented dosage forms (column 21-26). In particular, Unger et al. (USPN 5733572) teach the incorporation of **ethanol** for use in microsphere formulation. A skin absorption-enhancing agent **may also be incorporated into the gas and gaseous precursor filled microspheres** or into the aqueous media surrounding the gas and gaseous precursor filled microsphere structures. Such skin absorption enhancers include but are not limited to the following: alcohols such as **ethanol**, lauryl alcohol, linolenyl alcohol, 1-octanol, 1-propanol and 1-butanol; urea, cyclic unsaturated urea analogs, glycols, azone, n-alkanols, n-alkanes, orgelase, alphaderm cream and water. These may or may not be in a base which can be composed of various substances including but not limited to the following: glycerol, propylene glycol (PG); isopropyl myristate (1PM); urea in propylene glycol, **ethanol**, and

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water; and polyethylene glycol (PEG). Unger et al., further still, includes a disclosure (column 32, Example 16, lines 14-24), which teaches a filtration process by which the resultant **active ingredient** (unfiltered volume) yield a volume of 80-90% of the unfiltered volume.

Further, claims 1,3, 4, and 7 are rejected as being obvious over Unger et al., (5469854) further in view of Unger et al. (USPN 5770222, 6443898, and 6123923,).

Unger et al. (6443898) teach **microspheres** (**bead**, instant claim 3) that are disclosed to have a **semi-solid** consistency and are intended for use in a therapeutic drug delivery system [Detailed Description Text (87)].

Unger et al. (5770222) teach the final formation of gas-filled liposomes includ [ing] the transformation of the lipid to a **solid** form having a higher surface area, thus permitting better solubilization upon hydration and subsequently a higher yield of gas-filled liposomes [Detailed Description Text (101)].

Unger et al. (6123923) teach the incorporation of a **glycolic acid polymer** (film-forming material at the surface) so as to maintain stability of dosage form in association with solid matrices [Detailed Description Text (94)]. Further, Unger et al. teach **fiber** (instant claim 4) as a dosage form directed toward use as a **contrast agent** (instant claim 21) that is used in conjunction with **ultrasound** for surgical procedures [Drawing Description Text (10)].

Furthermore, instant claim 2 discloses a dosage form in the shape of a **cylinder**. The inner space of a needle (injection dosage form) cannula is shaped cylindrically, so as to accommodate various formulations that may be semi-solid within the needle

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housing, thereby properly addressing said limitation (instant claim 1, drawn toward injectable).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and devices of Hauschild et al. and Escanden et al. to include administration of a chemical ablation agent/biodisintegrable formulation for insertion or injection in view of the motivation of Unger et al. as disclosed above. There is substantial documentation in the prior art, which suggests the motivation via obviousness to combine the teachings of Hauschild et al. and Escanden et al. by reasonable explanation of producing an effective chemoablative/ therapeutic drug delivery system. It would instantly be obvious to one of ordinary skill in the art to see the motivation of Unger et al. in regard to disclosures/data supporting detailed explanations to purport the optimal scope of the subject invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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TEB


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